ENCLOSURE #2

K033478

DEC 2 9 2003

510(K) SUMMARY

December 15, 2003

CONTACT:

Douglas L. Harris
Greiner Vacuette North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICE:

Trade Name:	**VACUETTE**® QUICKSHIELD Safety Tube Holder
Common Names/Descriptions:	Evacuated Blood Collection Tube Holder
Classification Name:	Needle, Hypodermic, Single Lumen

PREDICATE DEVICE:

Becton Dickinson VACUTAINER® Brand ECLIPSE™ Blood Collection Needle (K982541)

DEVICE DESCRIPTION:

The VACUETTE® QUICKSHIELD Safety Tube Holder is to be used together only with VACUETTE® Multi-Sample Needles and VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

SUBSTANTIAL EQUIVALENCE:

The **VACUETTE**® QUICKSHIELD Safety Tube Holder is substantially equivalent to the Becton Dickinson VACUTAINER® Brand ECLIPSE™ Blood Collection Needle in intended use, materials, and overall performance characteristics.

In a study of 50 users, 500 **VACUETTE**® QUICKSHIELD Safety Tube Holders were used in simulated venipuncture. No failures of the safety shield were encountered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2003

Greiner Bio-One Vacuette North America, Incorporated
C/O Ms. Judi Smith
Principal
Sienna partners, L.L.C.
P.O. Box 103
Baldwin, Maryland 21013

Re: K033478
Trade/Device Name: Vacuette Quickshield Safety Tube holder
Regulation Number: 880.5570
Regulation Name: Hypodermic Single lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 31, 2003
Received: November 3, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCLOSURE #1 K033478

510(k) Number (if known): K033478

Device Name: VACUETTE® QUICKSHIELD Safety Tube Holder

Indications For Use:

The VACUETTE® QUICKSHIELD Safety Tube Holder is to be used together only with VACUETTE® Multi-Sample Needles and VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. This device is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033478

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)